

## REMARKS

This is in response to the action dated October 28, 2008.

### 1. Summary of Office Action

Claims 1, 2, 6 and 10 were rejected under 35 U.S.C. § 103(a) as being obvious in view of Reader et al., GB Patent No. 347,368 ("Reader").

Claim 3 was rejected under 35 U.S.C. § 103(a) as being obvious by a combination of Reader and Ishimaru et al. JP '076 ("Ishimaru").

Claims 7, 11, 19, 20, 22, 23 and 25-27 were rejected under 35 U.S.C. § 103(a) as being obvious in view of the references "as applied to claims 1,3 and 10" and Searer '896. However, since the rejection to Claim 1 and 10 is different than the rejection to Claim 3, the Applicant is unsure which references are being applied to Claims 7, 11, 19, 20, 22, 23 and 25-27. Clarification is requested. For purposes of this response, it is being assumed that Reader, Ishimaru and Searer are all being applied to Claims 7, 11, 19, 20, 22, 23 and 25-27.

Claims 4, 5, 13 and 24 were rejected under 35 U.S.C. § 103(a) as being obvious in view of the references "as applied to claims 1,2 and 19" and further in view of White '069. However, since the rejection to Claim 1 is different than the rejection to Claim 19, the Applicant is unsure which references are being applied to Claims 4, 5, 13 and 24. Clarification is requested. For purposes of this response, it is being assumed that Reader, Ishimaru, Searer and White are all being applied to Claims 4, 5, 13 and 24.

Claim 9 was rejected under 35 U.S.C. § 103(a) as being obvious in view of Reader and Morano '608.

Claim 12 was rejected under 35 U.S.C. § 103(a) as being obvious in view of Reader and Parkin '236.

Claims 28 and 29 were rejected under 35 U.S.C. § 103(a) as being obvious in view of the references as applied to claim 27 and Dunn '766. However, since the rejection to Claim 27 is not clear from the rejection (since the rejection to Claim 27 is based on references applied to Claims 1, 3, and 10, which involve different documents) the Applicant is unsure which references are being applied to Claims 28 and 29. Clarification is requested. For purposes of the response, it is being assumed that Reader, Ishimaru, Searer and Dunn are being applied to these claims.

Claims 32, 38, 54 and 60 were objected to, but were indicated as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant appreciates the Examiner's acknowledgement of the patentability of the claimed articles with a Shore A hardness of 5 and below.

Claims 14, 15, 30, 39, 42-53, 55 and 56 and 71 are allowed.

## **2. Remarks**

Claims 1, 2, 6 and 10 were rejected under 35 U.S.C. § 103(a) as being obvious in view of Reader et al., GB Patent No. 347,368 ("Reader"). Claim 1 now includes the subject matter of Claim 3 and therefore, this rejection is moot.

Under M.P.E.P. § 2142, the key to supporting any rejection under 35 U.S.C. § 103, there must be a clear articulation of the reason(s), with rational underpinning, to support the conclusion of obviousness. In particular, § 2142 explains: "The Supreme Court in *KSR International Co. v. Teleflex Inc.* [citation omitted] noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. The Federal Circuit has stated that 'rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval)."

As an initial matter, the M.P.E.P. points out that the analysis, "a clear articulation of the reason(s), with rational underpinning," to support a conclusion of obviousness must be made explicit.

"Mere conclusory statements" are insufficient to support a conclusion of obviousness.

However, in each of the remaining rejections made in the Action regarding the pending claims, the Action merely states that it would have been obvious to combine parts or structure from a first reference with a second reference (or further references).

For example, with respect to the rejection to Claim 3, which combines Reader and Ishimaru et al., the Action merely states that, "To have formed the nipple of a soft material with a Shore A hardness of less than about 10 in the manner of Ishimaru et al. would have been obvious." Since the Reader reference is a solid nipple formed of a hard rubber material and Ishimaru et al. is a hollow nipple made of a material having a hardness greater than 5, and there is no articulated reasoning with rational underpinning why one with ordinary skill in the art would combine these two different types of articles, the rejection has not been properly supported. In fact, there is nothing in either of these two references that would suggest combining the teachings of one with the other. Therefore, the rejections should be withdrawn with respect to all of the remaining rejections.

Moreover, all of the pending claims include the limitation of a substantially solid nipple being made of a material having a Shore A hardness of less than about 10 (or as in some allowed claims less than about 5). The Action lacks any articulated reasoning with rational underpinning explaining why one with ordinary skill in the art would arrive at these claimed features of the invention.

Reconsideration is requested.

Respectfully submitted,

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